Goodnet
510(k) Premarket Notification

12 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Submission in accordance with the requirements of 21 CFR Part 807.87(h)

Submitter	: Goodman Co., Ltd.
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Prepared	: February 16, 2001

2)	Device Name	: Goodnet
	Common Name	: Goodnet
	Device Class. Name	: System, Image Processing;
	Regulation Number	: 21 CFR 892.2050 (90 LLZ; Class II)

3) Predicate Device(s): DICOMVIEW manufactured by Heartlab, Inc.
510(k) Number: K954479, decision date 2/21/96

Description of the device:
Goodnet is a professional state-of-the-art Picture Archiving and Communication System, designed for use with Microsoft Windows operating systems (preferably, Windows NT). Goodnet facilitates the management of medical image files in a computer-based network, and includes facilities for incorporating visualization and analysis of medical images from other OEMs. Goodnet is designed for use by trained medical personnel (technologists, cardiologists, radiologists, other physicians, etc.). Goodnet may be used either independently or in conjunction with other FDA-certified software products from other OEMs.

5) Intended use:
Goodnet can be used in the traditional medical image archive and review applications, including cardiac cathetherization rooms, physician offices and other locations apart from the medical clinic or provider location.

6) Substantial equivalence Information:
Goodman believes the Goodnet system is substantially equivalent to the predicate device DICOMVIEW manufactured by Heartlab, Inc. (K954479) as both products employ the same technological characteristics and intended use.

Conclusion respecting safety and effectiveness:
It is the opinion of Goodman Co., Ltd. that Goodnet is safe. Potential hazards are controlled by a risk management plan for the software development process (Goodman is ISO 9001 certified, see Appendix C), including hazard analysis, verification and validation tests and evaluations by hospitals. In our opinion the level of concern for the Picture Archiving and Communication system to manage, archive and distribute images is minor and that the use of the Goodnet system does not change the intended use of the cardiology or radiology imaging systems in practice.

13 Indications for Use

Goodnet is designed for use in the creation and management of a database of archived medical images. Physicians and other medical personnel review and register images and patient information into the database. The database may be searched for specific data to identify image files of interest, using many search criteria as appropriate to the user. The image files may be reviewed or analyzed as desired. The database and image archive provide users with the capability for normal maintenance functions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 25 2001

Goodman Company, Ltd.
% Mr. Douglas F. Orr
J&M Group
109 Danbury Road
RIDGEFIELD CT 06877

Re: K010763
Goodnet
Dated: February 16, 2001
Received: March 14, 2001
Regulatory Class: II
21 CFR §892.2050/Procode: 90 LLZ

Dear Mr. Orr:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K010763

Device Name: Goodnet

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K010763